

**Legal, Ethical & Social Issues in Medical Informatics**  
**MED INF 407-DL**  
**Expanded Syllabus**

**Instructor:**

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**Course Description**

This course will present the legal and regulatory requirements applicable to healthcare data and information management systems, and stimulate critical thinking around selected topics related to the ethical and social impacts of information technology as they interface with the current healthcare regulatory environment. Some topics include HIPAA, medical ethics, fraud & abuse, data privacy and confidentiality, antitrust law, intellectual property issues, The Joint Commission, disclosure, transparency and accountability, compliance programs, including clinical research data compliance, healthcare data privacy and security regulations, and conflicts of interest.

**Course Objectives:**

- Identify Protected Health Information (PHI) and understand the range of permissible uses and disclosures allowed by HIPAA
- Develop ability to analyze, criticize and construct rigorous policy-oriented arguments for the appropriate handling of healthcare data
- Explain basic government regulations and legal principles applicable to healthcare data management, i.e. how to keep your CIO out of jail
- Summarize The Joint Commission's accreditation interest in medical informatics and data handling
- Identify the key components of an effective compliance program, including a demonstration of regulatory informatics
- Demonstrate critical thinking and thought leadership regarding future legal and ethical regulation of medical informatics in the U.S. social landscape.
- Basic facility with legal terminology to be in position to know when, and how, to consult effectively with corporate legal counsel

**Prerequisite:**

No previous background in law or medical ethics is necessary.

**Teaching Method:**

The 407 course content will be delivered in a combination of interactive Adobe Connect lectures with PowerPoint presentations; faculty-led class discussions; required and optional readings; class issue-spotting exercises; student presentations; student-led online debates on Blackboard's Discussion Board; and conversations with guest speakers.

The Instructor makes extensive use of the NU Blackboard for distributing class reading assignments, copies of PowerPoints, communicating with students, class participation evaluation (Discussion Board), grades, student work submissions, and more.

**Projects:**

Each student will be assigned three (3) projects during the course, with more details to be provided at the first class:

**1. Group Case Study:**

Participate in a group case study project, selected from a series of case studies provided to students, to be summarized in writing and presented to the class as if you were making a group presentation to a C-level executive (25%);

**2. Criticism Project:**

Read an older journal article relating to medical informatics (selected from a list to be provided), and write a thoughtful response to the article, including a rigorous critique and update of the author's premise/conclusions by applying the legal, ethical and social concerns learned in class (20%); and

**3. Research Paper:**

Write a research paper that presents a detailed forward-thinking proposal to improve upon some aspect of the legal regulation of healthcare data and/or information management systems, including taking a critical look at the relevant history of that legal issue, the current state, and most importantly the future state as envisioned by the student (25%).

**Evaluation Method**

Students will be evaluated by:

- Projects: 70%
- Class participation, including Discussion Board, issue-spotting exercises and in-class: 30%

**Northwestern University Grading Scale:**

A 95-100

A- 90-94

B+ 88-89

B 83-87

B- 80-82

MMI Acceptable

C+ 78-79

C 73-77

C- 70-72

F below 70

**Course Readings:**

There is no textbook for the MMI 407 course; however, students are expected to have read certain materials in advance of the first class (to be posted by Instructor prior to the start of the quarter), with further required readings to be assigned as the course moves forward.

**Synchronous Sessions:**

For the online MMI 407 course, all scheduled synchronous sessions (i.e. Adobe Connect) will be held on Wednesday nights, unless otherwise indicated.

**Instructor's Office Hours and Availability:**

Office hours will be held by prior appointment only. There also will be an Instructor's Q&A Forum on the Blackboard Discussion Board for easy access to the Instructor for questions or concerns of general interest to the class. Otherwise, feel free to call or email the Instructor directly with more individual student questions or concerns.

Session	Readings Note: Links to all articles and websites can be found in the course on the <i>Reading and Materials</i> page for the session in which they're assigned	Assignments	Synchronous Meeting(s) CDT
<b>1</b> <b>The American Legal System and Foundations of Law and Ethics</b>	<b>Required</b> <ul style="list-style-type: none"> <li>• History and Organization of State Judicial System</li> <li>• Federal Judicial System</li> <li>• Chapter Introduction to Outline of US Legal System</li> <li>• HIPAA Patient Identifiers</li> <li>• Privacy, Security and the Regional Health Information Organization</li> <li>• The HIPAA Paradox</li> </ul> <b>Discussion Board</b> <ul style="list-style-type: none"> <li>• Public Policy Analysis</li> <li>• Homeland Security and HIM (AHIMA)</li> <li>• Summary of the HIPAA Privacy Rule</li> <li>• Toward a National Framework for the Secondary Use of Health Data</li> </ul>	<b>Assignments</b> Introduction to Project 1: Group Case Study  Weekly discussion leaders assigned  Class Issue-Spotting Exercise Introduction	Wednesday, Sept. 23rd from 7-9pm
<b>2</b> <b>Healthcare Data: Privacy and Security Issues for Informaticists</b>	<b>Required</b> <ul style="list-style-type: none"> <li>• How to Approach the Final HIPAA Security Regulations</li> <li>• Research Under HIPAA</li> </ul> <b>Discussion Board</b> <ul style="list-style-type: none"> <li>• JAMA Reforming HIPAA Privacy Rule</li> <li>• Top 10 Ways to Protect From Data Security Threats</li> <li>• First HIPAA Covered Entity Settles with Government</li> <li>• Are Troublesome HIPAA Changes of the Way?</li> <li>• Employees Have Right to Privacy in Text messages</li> <li>• Remote Use of ePHI</li> <li>• Report from the Health Information Protection Taskforce to the State Alliance for e-Health</li> </ul>	<b>Assignments</b> Class Issue-Spotting Exercise	Wednesday, Sept. 30th from 7-9pm

<p><b>3</b> <b>Fraud and Abuse Issues and Compliance Programs</b></p>	<p><b>Required</b></p> <ul style="list-style-type: none"> <li>• Conflicts of Interest in Human Subject Research</li> <li>• Health Data Access, Use, and Control (AHIMA)</li> <li>• Hospitals Cautious About Subsidizing EMR Adoption Despite Relaxed Federal Rules</li> <li>• Overview of Organizational Sentencing Guidelines</li> </ul> <p><b>Discussion Board</b></p> <ul style="list-style-type: none"> <li>• Current Issues Under the Civil False Claims Act</li> <li>• Healthcare Fraud &amp; Abuse 101</li> </ul>	<p><b>Assignments</b></p> <p>Class Issue-Spotting Exercise</p> <p>Introduce Project #2: Criticism Paper</p>	<p>Wednesday, Oct. 7th from 7-9pm</p>
<p><b>4</b> <b>Group Case Study Presentations</b></p>	<p><b>Required</b></p> <ul style="list-style-type: none"> <li>• How to Launch a Data Governance Program (INFORMATICA)</li> <li>• The State of RHIOs</li> </ul> <p><b>Discussion Board</b></p> <ul style="list-style-type: none"> <li>• Securing eHealth records Without Impeding Flow of Information</li> <li>• The Role of Ethics in IT Decisions</li> </ul>	<p><b>Assignments</b></p> <p>Individual Case Study Paper</p> <p>Group Presentations during the synchronous session</p> <p>Individual Peer Assessment on Group Case Studies</p>	<p>Wednesday, Oct. 14th from 7-9pm</p>
<p><b>5</b> <b>Intellectual Property Issues</b></p>	<p><b>Required</b></p> <ul style="list-style-type: none"> <li>• “Fair Use” of Copyrighted Works</li> <li>• Summary of IP Protections</li> <li>• Understanding the importance of Derivative Works</li> </ul> <p><b>Discussion Board</b></p> <ul style="list-style-type: none"> <li>• Advanced Copyright Issues on the Internet</li> <li>• Clean Rooms are Not Just for Kids: How to demonstrate independent development to avoid a trade secret lawsuit</li> </ul>	<p><b>Assignments</b></p> <p>Introduction to Project 3: Research Paper</p> <p>Class Issue-Spotting Exercise</p>	<p>NO SYNCH SESSION THIS WEEK</p>

<p><b>6</b> <b>Ethical and Social Issues and Interactive Class Discussion of Ethics Case Studies</b></p>	<p><b>Required</b></p> <ul style="list-style-type: none"> <li>• The Principle of Autonomy</li> <li>• Beneficence</li> <li>• Bioethics and Health Informatics</li> <li>• Ethics and EHRs</li> <li>• Ethical Dimensions in Public Reporting of Clinical Performance Data</li> <li>• Justice</li> <li>• Non-Maleficence</li> </ul> <p><b>Discussion Board</b></p> <ul style="list-style-type: none"> <li>• AHRQ National Health Data Stewardship</li> <li>• Forms of Ethical Reflection</li> </ul>	<p><b>Assignments</b></p> <p>Class Ethics Case Study Example</p>	<p>Wednesday, Oct. 28th from 7-9pm</p>
<p><b>7</b> <b>The Joint Commission and Medical Informatics</b></p>	<p><b>Required</b></p> <ul style="list-style-type: none"> <li>• Summary Rewarding Provider Performance</li> <li>• TJC Measurement Data</li> </ul> <p><b>Discussion Board</b></p> <ul style="list-style-type: none"> <li>• Rewarding Provider Performance</li> <li>• TJC Data Activities Chronology</li> </ul>	<p><b>Assignments</b></p> <p>Project 2: Criticism papers due</p>	<p>NO SYNCH SESSION THIS WEEK</p>
<p><b>8</b> <b>Antitrust Issues Arising from Data Handling</b></p>	<p><b>Required</b></p> <ul style="list-style-type: none"> <li>• Legal Process and Electronic Health Records</li> <li>• Maintaining a Legally Sound Health Record</li> <li>• Antitrust Watch on Standard Setting Organizations (SSOs): Fox in the Henhouse?</li> </ul> <p><b>Discussion Board</b></p> <ul style="list-style-type: none"> <li>• EHR Guidelines to Prevent Fraud</li> <li>• Legal Issues and eHealth in the EU</li> <li>• Legal Obstacles to eHealth</li> </ul>	<p><b>Assignments</b></p> <p>Class Issue-Spotting Exercise</p>	<p>Wednesday, Nov. 11th from 7-9pm</p>
<p><b>9</b> <b>Overview of Regulatory Informatics and Live Interactive Regulatory Informatics Demonstration</b></p>	<p><b>Discussion Board</b></p> <ul style="list-style-type: none"> <li>• Cloud Computing Security Risks</li> <li>• Legal Issues with Cloud Computing</li> </ul>	<p><b>Assignments</b></p>	<p>Wednesday, Nov. 18th from 7-9pm</p>
<p><b>10</b> <b>Research Paper</b></p>	<p>There is no assigned reading for this session.</p>	<p><b>Assignments</b></p> <p>Project 3: Research paper</p>	<p>NO SYNCH SESSION THIS WEEK</p>

## **University Policy**

### **Students with Disabilities**

In compliance with Northwestern University policy and equal access laws, we are available to discuss appropriate academic accommodations you may require as a student with a disability. Request for academic accommodations need to be made during the first week of the quarter, except for unusual circumstances, so arrangements can be made. Students are encouraged to register with Services for Students with Disabilities (SSD) for disability verification and for determination of reasonable academic accommodations. For more information, visit <http://www.northwestern.edu/disability/>

### **Academic Integrity at Northwestern**

Students are expected to comply with University regulations regarding academic integrity. If you are in doubt about what constitutes academic dishonesty, please speak to us before the assignment is due and/or examine the University web site, "How to Avoid Plagiarism at <http://www.northwestern.edu/uacc/plagiar.html>

Academic dishonesty includes, but is not limited to cheating on an exam (e.g., copying others' answers, providing information to others, using a crib sheet) or plagiarism of a paper (e.g., taking material from readings without citation, copying another student's paper). Failure to maintain academic integrity on an assignment will result in a loss of credit for that assignment – at a minimum. Other penalties may also apply. For more information, visit [http://www.scs.northwestern.edu/student/issues /academic\\_integrity.cfm](http://www.scs.northwestern.edu/student/issues /academic_integrity.cfm)

### **Sexual Harassment Policy**

It is the policy of Northwestern University that no male or female member of the Northwestern community – students, faculty, administrators or staff – may sexually harass any other member of the community. Sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature constitute harassment when: submission to such conduct is made or threatened to be made, either explicitly or implicitly, a term or condition of an individual's employment or education; or submission to or rejection of such conduct is used or threatened to be used as the basis for academic or employment decisions affecting that individual; or such conduct has the purpose or effect of substantially interfering with an individual's academic or professional performance or creating what a reasonable person would sense as an intimidating, hostile, or offensive employment, educational, or living environment. For more information, visit <http://www.northwestern.edu/sexual-harassment/policy/index.html>